K092378

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

NOV - 2 2009

Proprietary Name:	Visisheath™ Dilator Sheath
Common Name:	Dilator sheath
Classification Name:	dilator, vessel, for percutaneous catheterization
Device Classification:	Class II
Product Classification and Code:	21 CFR 870.1310, DRE
Classification Panel:	Cardiovascular Devices
Establishment Registration Number:	3007284006
Contact Person:	Cheryl Hastings Regulatory Affairs Spectranetics Corporation 9965 Federal Drive Colorado Springs, CO 80921 Telephone: (719) 659-1848 Facsimile: (719) 447-2040 E-mail: *Cheryl.hastings@spnc.com*

Performance Standards

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The VisiSheath™ Dilator Sheath is a single lumen polymer sheath used independently or as a support for an inner sheath to facilitate tissue dilation. One end is terminated with a 45° angle cut, while the other end is blunt. Both ends contain a metallic radiopaque marker band to enable fluoroscopic identification of tip location and orientation. An additional exterior mark aligned with the tip of the 45° angle cut permits visual identification of sheath orientation. There are multiple diameter and length options available.

Indication for Use

The VisiSheath™ Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects. The device is also intended for use in the introduction and support of intravascular catheters.

Substantially Equivalent Devices

In Spectranetics' opinion, the VisiSheath™ Dilator Sheath is believed to be substantially equivalent to the predicate device.

Summary of Studies

Spectranetics performed device functional testing to support that the VisiSheath™ Dilator Sheath functions as intended. All device functional test results for the VisiSheath™ Dilator Sheath met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the Spectranetics VisiSheath™ Dilator Sheath through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Spectranetics Corp.
ATTN: Cheryl Hastings
Regulatory Affairs and Compliance Manager
9965 Federal Drive
Colorado Springs, CO 80921

NOV - 2 2009

Re: K092378
Trade/Device Name: Spectranetics VisiSheath Dilator Sheath
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: July 24, 2009
Received: August 19, 2009

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

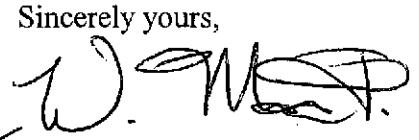
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number _K092378

Device Name: Spectranetics VisiSheath™ Dilator Sheaths

Indications for Use:

The VisiSheath Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects. The device is also intended for use in the introduction and support of intravascular catheters.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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